IMPROVING CANCER CLINICAL TRIALS DURING COVID-19 AND BEYOND

Clinical trials are critical for progress against cancer. Although the ongoing COVID-19 pandemic has disrupted many aspects of cancer clinical trials, all stakeholders have come together and responded in unprecedented ways to continue clinical research. Remarkable changes to the conduct of clinical trials have been proposed and/or implemented, many of which may be continued beyond the pandemic. The suggested changes are designed to ensure a patient-centric approach and to enhance patient safety and experience while improving clinical trial efficiency and outcomes. Some of the changes have the potential to improve long-standing challenges in clinical trials such as low enrollment of patients and a lack of diversity among those who do participate. Below are some examples of such recommendations across the various stages of the clinical trial process:

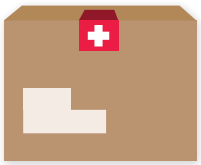
Clinical trial design and regulation:

- Prioritize and streamline the primary endpoints of the trial
- Enable remote trial monitoring
- Enable flexible electronic and remote consent

Patient enrollment (trial eligibility and screening):

- Reduce nonessential screening assessments
- Limit "in-person" screening assessments to a single visit
- Permit virtual visits and decentralized assessments

Delivery of care:



- Permit and train for low-risk therapeutic administration at home
- Implement easier routes of delivery of therapeutics, e.g., oral instead of intravenous
- Ship therapeutics to patient's home to minimize time in study center
- Use telemedicine when appropriate

Assessment of safety and efficacy:

- Reassess the need for and frequency of safety and efficacy assessments
- Direct patient reporting of symptoms/adverse effects
- Allow for diagnostic testing such as bloodwork/imaging to be performed locally to patients and when possible incorporated as part of regular clinical care
- Increase use of telemedicine
- Implement alternative safety assessment methods (for example, wearable technologies)
- Permit decentralized efficacy assessments in non–study centers and review centrally
- Consider surrogate efficacy markers (e.g., ctDNA and tumor markers)